

Appl. No. 09/692,634
Atty. Docket No.8308
Customer No. 27752

REMARKS

Claim Status

Claims 1-7, 20-27, and 30-37 are pending.

Objection to the Specification

The Examiner has objected to the specification namely page 5, lines 17-34. Applicants have amended the specification per the Examiners suggestions. Accordingly, reconsideration and withdraw of the objection is respectfully requested.

Under 35 USC 103(a) Over Deihl EP 0505374,in view of Makino et al. US 4,789,667 and Kuhrt et al. Virucidal Activity of Glutaric Acid and Evidence for Dual Mechanism of Action

Claims 1-7, 20-27, and 30-37 have been rejected under 35 USC 103(a) as being unpatentable over Deihl EP 0505374, in view of Makino et al. US 4,789,667 and Kuhrt et al. Virucidal Activity of Glutaric Acid and Evidence for Dual Mechanism of Action. The Examiner states that Deihl discloses a pharmacological composition for the treatment of the common cold by spraying said composition into the oral cavity. The composition comprises vitamin C and a non-toxic zinc salt. The Examiner states that Makino discloses a pharmaceutical composition for external use with enhanced pharmacologically active agent through the skin and that the composition comprises a pharmacologically active agent and an optically active or inactive pyroglutamic acid ester. The Examiner then states that Kuhrt discloses that Rhinovirus as a group is notably sensitive to inactivation in solutions with a pH of less than 5.3. Applicants respectfully traverse this rejection based on the remarks contained herein.

Deihl discloses a composition that provides vitamin C in the manufacture of a pharmacological composition that can be used to treat common colds. Diehl does not teach or suggest a method for treating cold or influenza viruses wherein the method comprises the step of spraying into the nasal turbinates a composition comprising: pyroglutamic acid and an organic acid having a dissociation constant (pKa) value from about 3.0 to about 5.0; and a pH adjusting agent; wherein the composition is a homogeneous liquid solution having a pH value from about 3.5 to about 5.5 on the nasal

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tissues. Deihl never teaches or suggest a pH or that the pH of the nasal tissue when the solution is delivered to the nasal tissue is 3.5 to about 5.5 on the nasal tissue.

Additionally, Deihl never teaches or suggest that the pharmacological composition comprise a pH adjusting agent or pyroglutamic acid.

Makino discloses a pharmaceutical composition for external use that provides for enhanced penetration or permeation of drugs. Makino discloses that pyroglutamic acids can be used to aid in penetration of the drug. Makino fails to teach or suggest a method a treating the common cold pyroglutamic acid and an organic acid having a dissociation constant (pKa) value from about 3.0 to about 5.0; and a pH adjusting agent; wherein the composition is a homogeneous liquid solution having a pH value from about 3.5 to about 5.5 on the nasal tissues. The present invention utilizes pyroglutamic acid in combination with organic acids to create a hostile environment on the surface of the nasal cavity not for the delivery of drug that penetrate a mucosa.

Kuhrt discloses a study to determine if the virucidal activity of glutaric acid is solely due to low pH of a solution in which it is tested or to the intrinsic property of the chemical entity. Kuhrt discloses in the summary of the test that glutaric acid appears to inactive RV-14 and several other strains of human rhinovirus by a mode of action independent of acidic pH at low temperatures and that the acidulant effect at room temperature is not detectable. (See page 927, last paragraph). Kuhrt does not teach or suggest a method a treating the common cold pyroglutamic acid and an organic acid having a dissociation constant (pKa) value from about 3.0 to about 5.0; and a pH adjusting agent; wherein the composition is a homogeneous liquid solution having a pH value from about 3.5 to about 5.5 on the nasal tissues. Kuhrt does not teach or suggest a homogeneous solution that has a pH of 3.5 to about 5.5 on the nasal tissue.

Assuming *arguendo* that one having ordinary skill in the art would combine the disclosures of Deihl, Maniko et al. and Kuhrt et al., one would still fall short of the of Applicants' claimed invention only to arrive at a composition that comprises vitamin C, glutaric acid and zinc that utilizes pyroglutamic acid to enhance drug delivery and inactivates RV-14 and several other strains of human rhinovirus by a mode of action independent of acidic pH at low temperatures.

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The combination of Deihl, Maniko et al. and Kuhrt et al., do not teach or suggest each and every element of Applicants' presently claimed invention i.e. a method of treating the common cold pyroglutamic acid and an organic acid having a dissociation constant (pKa) value from about 3.0 to about 5.0; and a pH adjusting agent; wherein the composition is a homogeneous liquid solution having a pH value from about 3.5 to about 5.5 on the nasal tissues.

Accordingly, Claims 1-7, 20-27, and 30-37 are novel over the prior art of record. Reconsideration and withdrawal of the rejection on this basis are requested.

Conclusion

In light of the remarks and amendments presented herein, Applicants respectfully submit Claims 1-7, 20-27, and 30-37 are allowable over the cited reference. Reconsideration and allowance are respectfully requested. In the event that issues remain prior to allowance of the noted claims, then the Examiner is invited to call Applicant's undersigned attorney for further discussion.

Respectfully Submitted,

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